K080664 (pg. 1 of 1)

510(k) SUMMARY: RELIEVE™ Laminoplasty Fixation System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

JUL 2 5 2008

Device Name: RELIEVE™ Laminoplasty Fixation System

Classification: Product Code NQW. Class II.
21 CFR §888.3050 Spinal interlaminal fixation orthosis.

Predicate(s): Medtronic Sofamor Danek CENTERPIECE Plate Fixation System K050082; Blackstone Laminoplasty Fixation System K043338, and Synthes Arch Fixation System K032534.

DEVICE DESCRIPTION:

The RELIEVE™ Laminoplasty Fixation System consists of spinal fixation plates and screws for use in laminoplasty procedures. RELIEVE™ implants are inserted through a posterior cervical or thoracic approach, and are available in various sizes and geometric options to fit individual patient anatomy. Plates may be filled with bone graft material. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy.

RELIEVE™ plates are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in F2026, F136, F1295, and F560. Screws are made from titanium alloy, as specified in F136 and F1295.

INTENDED USE:

The RELIEVE™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The RELIEVE™ Laminoplasty Fixation System is used to hold the bone allograft material in place in order to prevent the allograft from expulsion, or impinging the spinal cord.

Basis for Substantial Equivalence:
RELIEVE™ Laminoplasty Fixation System is similar in terms of indications, design, materials, and performance, to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2008

Globus Medical, Inc
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K080664
Trade/Device Name: RELIEVE™ Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: May 30, 2008
Received: June 02, 2008

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080664

Device Name: RELIEVE™ Laminoplasty Fixation System

INDICATIONS:

The RELIEVE™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The RELIEVE™ Laminoplasty Fixation System is used to hold bone allograft material in place in order to prevent the allograft from expulsion or impinging the spinal cord.

Prescription Use ___X___ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080664